K102617

Aalto Scientific, Ltd.

510(k) Summary

JAN 10 2011

A. Submitter

Aalto Scientific, Ltd.
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B. Contact Person

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C. Date of Summary Preparation

December 23, 2010

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Cardiac Markers Linearity Set
Common Name:	Calibration Verification
Classification Name:	Multi analyte controls (Assayed and Unassayed)
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

E. Device to Which Substantial Equivalence is claimed

Product Trade Name:	Audit MicroCV General Chemistry Linearity Set Aalto Scientific, Ltd., Carlsbad, California K042318

F. Description of the Device

The Audit™ MicroCV™ Cardiac Markers Linearity Set is a 5 level quality control solution set containing CKMB, Myoglobin, and TnI analytes as the messurand. It is used to confirm the proper calibration, linear operating range, and reportable range of CKMB, Myoglobin, and TnI analytes. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

Statement of Intended Use

The Audit™ MicroCV™ Cardiac Markers Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains CKMB, Myoglobin, and Troponin I (TnI) analytes. The five levels demonstrate a linear relationship to each other for CKMB, Myoglobin, and TnI analytes. When Audit™ MicroCV™ Cardiac Markers Linearity Set is used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the analyzers indicated in the labeling. The Audit™ Cardiac Markers Linearity Set is "For In Vitro Diagnostic Use Only".

I. Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Audit™ MicroCV™ Cardiac Markers Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Open Vial Stability: Once a vial has been reconstituted, all analytes will be stable for 5 days when stored tightly capped at 2-8 C.

Shelf Life: 18 months at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™ Cardiac Markers Linearity Set (New)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	The Audit™ MicroCV™ Cardiac Markers Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains CKMB, Myoglobin, and Troponin I (TnI) analytes. The five levels demonstrate a linear relationship to each other for CKMB, Myoglobin, and TnI analytes. When Audit™ MicroCV™ Cardiac Markers Linearity Set is used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the analyzers indicated in the labeling. The Audit™ Cardiac Markers Linearity Set is "For In Vitro Diagnostic Use Only".	Audit® Micro*CV*™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments[1]. This product may also be used as unassayed quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. In addition, it may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification[2] for these same analytes in accordance with current CLIA-88 guidelines and regulations[3].
Number of levels per set	5	5
Contents	5 x 1mL	5 x 5mL
Matrix	Human Serum	Human Serum
Type of Analytes	CKMB, Myoglobin, and Troponin I (TnI)	Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid.
Form	Lyophilized	Lyophilized
Storage	2 to 8° C for 18 months	2 to 8° C for 48 months
Open Bottle Stability	5 days at 2 to 8° C	7 days at 2 to 8° C

J. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Aalto Scientific Ltd.
c/o Dessi Lyakov
1959 Kellogg Ave.
Carlsbad, CA 92008 USA

Re: k102617
Trade Name: Audit™ MicroCV™ Cardiac Markers Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJY
Dated: November 22, 2010
Received: November 23, 2010

JAN 10 2011

Dear Ms. Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976,Ythe enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number: New

Device Name: Audit™ MicroCV Cardiac Markers Linearity Set

Indications For Use:

The Audit™ MicroCV™ Cardiac Markers Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains CKMB, Myoglobin, and Troponin I (TnI) analytes. The five levels demonstrate a linear relationship to each other for CKMB, Myoglobin, and TnI analytes. When Audit™ MicroCV™ Cardiac Markers Linearity Set is used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the analyzers indicated in the labeling. The Audit™ Cardiac Markers Linearity Set is "For In Vitro Diagnostic Use Only".

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

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